UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,676	08/28/2003	Joseph Utermohlen	191/001/DIV1	2546

23874 7590 05/17/2006

VENTANA MEDICAL SYSTEMS, INC.
ATTENTION: LEGAL DEPARTMENT
1910 INNOVATION PARK DRIVE
TUCSON, AZ 85755

EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,676	UTERMOHLEN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/15/05, 3/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 8/23/2003 has been entered. Claims 9-18 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 9-18 are vague and indefinite because the preamble states that the method is automatically hybridizing a polynucleotide probe to a target, but the method steps do not involve automatic steps. Clarification is required.

b. Claim 16 is vague and indefinite because of the phrase "with blocking DNA". It is unclear what is encompassed by the phrase. Clarification is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz (4,886,741, issued December 12, 1989).

Schwartz et al. disclose using volume exclusion agents to enhance in situ hybridization rates between short oligonucleotide probe and their target polynucleotides where the cells

containing the target polynucleotide are adhered onto a glass substrate (See the Abstract, column 2, lines 30-35). One of the volume exclusion agents is dextran sulfate (See column 3, lines 1-3 column 6, lines 31-33, column 10, lines 25-26). The tissues are prepared by ~~frozening~~ freezing, perfusion and embedding with paraffin prior to sectioning (See column 3, lines 67-68). The probe is labeled with fluorophores (See column 5, lines 24-25).

Since the limitations do not indicate that each step of the method is done automatically, and there is no definition regarding the molecular weight of dextran sulfate and the coding region of the target, the teachings of Schwartz et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (4,886,741, issued December 12, 1989) as applied to claims 9-15 above, and further in view of Gray et al. (5,447,841, issued September 5, 1995).

The teachings of Schwartz are set forth in section 4 above. Schwartz does not disclose contacting the target RNA or DNA with blocking DNA to suppress background cross-reactive signal.

Gray et al. disclose staining target chromosomal DNA comprising using blocking DNA. The blocking DNA is complementary to repetitive segments in a labeled nucleic acid, which is complementary to the chromosomal DNA (See column 17, lines 4-25).

One of ordinary skill in the art would have been motivated to apply the blocking DNA of Gray et al. to the in situ hybridization of Schwartz to make the instant invention because by applying the blocking DNA it is sufficient to permit detection of hybridized labeled nucleic acid containing segment (See column 17, lines 20-25). It would have been prima facie obvious to apply the blocking DNA in situ hybridization.

7. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (4,886,741, issued December 12, 1989) as applied to claims 9-15 above, and further in view of Towne et al. (6,855,552, issued February 15, 2005).

The teachings of Schwartz are set forth in section 4 above. Schwartz does not disclose that hybridization, removal and detection steps are performed by an automated tissue-staining instrument and the probe composition is arrayed on a solid substrate.

Towne et al. disclose automated immunohistochemical and in situ hybridization assay (See the Abstract and column 4, lines 49-63). The method of Towne et al. comprises automatic

hybridization, removal and detection steps (see entire document). Towne et al. also disclose that biological sample includes tissue arrays (See column 14, lines 8-14). This teaching suggests that after hybridization on a target, the probe composition is arrayed on a solid substrate.

One of ordinary skill in the art would have been motivated to apply the automated immunohistochemical and in situ hybridization assay of Towne et al. to the method of Schwartz because the automated immunohistochemical and in situ hybridization assay improves stainability and interpretation of test data (See column 4, lines 35-40). It would have been prima facie obvious to perform hybridization, removal and detection steps by an automated tissue staining instrument.

Summary

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung J.T.
May 6, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/15/06